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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,099	08/23/2001	Rajiv Indravadan Modi	CAPH 8016US	2239

7590 10/30/2003

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EXAMINER

MELLER, MICHAEL V

ART UNIT PAPER NUMBER

1654

DATE MAILED: 10/30/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,099

Applicant(s)

MODI ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-16, 18, 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific microorganisms listed in claim 3 and the specific anti-infective agents listed in claim 2, does not reasonably provide enablement for any and all anti-infective agents and any and all microorganisms susceptible to the anti-infective agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant's specification provides enablement for the specifically claimed anti-infective agents and microorganisms. Applicant's specification does not provide support to claim any and all anti-infective agents and any and all microorganisms "susceptible" to the anti-infective agents. First of all, what is meant by "susceptible" ? The word

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susceptible is very broad in meaning. One can be susceptible to a cold, but that does not mean that one will get a cold. Applicants have shown that list of specific antibiotics work with a specific set of microorganisms. For applicant to claim such broad lists of these is simply without merit since one of ordinary skill in the art would not be able to identify all of the species in these genera. Knowing only these specific microorganisms and these specific antibiotics would at best produce a short list of possible combinations, but how can applicant expect one of ordinary skill in the art to figure out each and every microorganism that might be susceptible to the anti-infective agents. Furthermore, just about every microorganism would be susceptible to an anti-infective agent since the term "susceptible" is vague and indefinite to begin with.

Also, it is important to note that the field of biotechnology is so unpredictable that one would not necessarily know if any and all microorganisms susceptible to the anti-infective would work. Microorganisms are living beings and are therefore, by definition unpredictable and cannot be relied upon to necessarily work with antibiotics to yield applicants results as disclosed in the instant specification.

Further, applicant has no support for "a broad spectrum antibiotic" ? Applicant has support for what was discussed above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 and 18, 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention for the reasons of record and for the reasons which follow.

Claim 1 is still very confusing. It might be clearer if applicant were to claim the invention as, " A stable fixed dose oral pharmaceutical formulation comprising:

a) at least one...., and

b) at least one"

This way applicant can simply refer to each component as "a)" or "b)" instead of "a first ingredient" or "a second ingredient" since that simply adds to the confusion.

With regards to the powder concern, remington's definition applies to one ingredient or mixture, not when one is coated and not intended to contact the other.

What is mean by "susceptible" ? This term is vague and indefinite. One may be susceptible to a cold but that does not mean that one will get one. Microorganisms are susceptible to all kinds of problems and antibiotics are no exception.

In terms of the coating in claim 15, it is not clear where it is ? What kind of coating. Will paint do it ? Shouldn't the coating prevent the microorganism from contact from the anti-infective agent otherwise the whole invention is for not. This is a very confusing claim.

Claim 16 fails to further limit claim 15.

Claim 18 is confusing since it is not clear what "at least one of the first and second active ingredient" refers to. Is the coating on both of them. And if it is how can

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they be then separated. Further, if they are both in granular form, how can they be in layers or physically separated from one another.

Claim Rejections - 35 USC § 102

Claims 1, 3, 6-8, 15, 16, 18, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 6855.

Applicant argues that this reference teaches that the microorganism is not susceptible to the anti-infective agent. Applicant provided Finch. Even Finch admits that streptococci are susceptible to tetracycline. Thus, applicants arguments really are without merit.

Further, as noted before by Hawley's, tetracycline is a known antibiotic and the last time the examiner checked, *lactobacillus* and the others were bacteria.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by FR 5247.

Applicant relies on the same arguments as above. Thus, the response is the same as above.

Claim Rejections - 35 USC § 103

Claims 1-16, 18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 5247 in view of FR 6855 and further in view of Black et al.

Applicant argues essentially the same as above. Black was cited to show that ampicillin is also well known to be used for the same purpose as in the disclosed invention. One of ordinary skill in the art would have been motivated to use ampicillin instead of tetracycline since Black yielded such beneficial results.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Black was used as part of the 35 USC 103 rejection and was not used under 35 USC 102 as argued by applicant. Applicant cannot expect Black to contain all of applicant's invention. It was used as a secondary reference which is clear from the record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M V Meller', followed by a horizontal line.

Michael V. Meller
Primary Examiner
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MVM